In re application of:

Gunter A. Hofmann, et al

Gerial No.: 08/467,566

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For: NEEDLE ELECTRODES FOR MEDIATED DELIVERY OF DRUGS AND GENES

Examiner: M. Bockelman

Atty Docket: 15-44

Group Art Unit: 3306

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

CERTIFICATE OF MAILING

37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below:

8/14/96 Michaele S. Malender Date Signature

DECLARATION OF GUNTER A. HOFMANN

I, Gunter A. Hofmann, declare as follows:

The Subject Invention

I am a joint inventor of the above-captioned patent application.

This invention relates to the direct insertion of genes and pharmaceuticals into cells of a patient by way of a method called electroporation. One embodiment of the invention comprises an apparatus consisting of a support member, a plurality of needle electrodes adjustably mounted on said support member for insertion into tissue at selected positions and distances from one another, and means including a signal generator responsive to said distance

signal for applying an electric signal to the electrodes proportionate to the distance between said electrodes for generating an electric field of a predetermined length.

The Subject Invention Contributes To The Treatment Of Cancer

The present application should be made "special" and advanced out of turn for examination because the subject invention contributes to the effective treatment of cancer.

The present invention contributes to the treatment of cancer by providing an improved method and apparatus for the application of controlled electric fields for in vivo delivery of cancer treating compounds into live cells of a patient by electroporation.

Electroporation is a treatment by which electric fields are applied to cancerous tissue thus making possible the insertion of an anticancer drug directly into malignant cells without harming healthy cells. In order to prevent damage to healthy cells, the electric field must be applied reasonably accurately. Therefore, it is necessary to apply two electrodes into or adjacent a tumor and measure the distance between them so that a suitable voltage can be applied. This can normally be easily carried out with external tumors by applying electrodes to opposite sides of the tumor so that the electric field is between the electrodes. However, current technology lacks the ability to apply electrodes, and measure the distance between them, when confronted with an internal tumor.

The present invention alleviates this hardship in cancer treatment by providing a method and apparatus having electrodes that can be inserted into or adjacent tumors so that predetermined electric fields can be generated in the tissue for electroporation of the cancerous cells of the tumor. Thus, cancer treating compounds can be inserted directly into

the malignant cells without harming healthy cells.

Conclusion

In summary, the present application should be made special because the subject invention materially contributes to the treatment of cancer.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the Unite States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 8/12/1556

Gunter A. Hofmann